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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,279	01/04/2002	Luc Schoonjans	4029-012233	8191

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EXAMINER	
PARAS JR, PETER	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,279	SCHOONJANS ET AL.	
	Examiner	Art Unit	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 39-47* is/are pending in the application.

4a) Of the above claim(s) *21-23 and 39-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) *21-23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 May 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *0902, 1202* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-23 and 39-47 are pending.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-23, in response received on 11/12/03, is acknowledged.

Newly submitted claims 39-47 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are directed to embryonic stem cell lines. Embryonic stem cell lines were set forth as claims linking Groups II and III in the restriction requirement mailed on 9/9/03.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 39-47 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Priority

Applicants must update the status of applications 09/891,913 and 09/628,833 as recited in the priority statement beginning on line 1 of the specification.

Drawings

New corrected drawings are required in this application because the drawing submitted on 5/13/02 contains handwritten text. Applicant is advised to employ the

services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

Claim 21 (and claims 22-23 which depend therefrom) is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to the claims it depends from in the alternative. See MPEP § 608.01(n). Accordingly, the claims (21-23) have not been further treated on the merits.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 19 embraces a fibroblast cell line deposited with the Belgian Coordinated Collection of Microorganisms, under accession number LMBP 5479 CB.

The invention appears to employ a novel fibroblast cell line (LMBP 5479 CB). The specification has disclosed that the fibroblast cell line has been deposited. See pages 7 of the specification. However, it appears that the deposit requirements have not been perfected. Since the fibroblast cell line is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the fibroblast cell line is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the fibroblast cell line. See 37 CFR 1.802. A deposit is required for purpose of enablement. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. See 37 CFR 1.808. Such a statement or affidavit or declaration has not been provided.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.808, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a viability statement in accordance with the provisions of 37 CFR 1,807; and

(e) the deposit will be replaced if it should ever become unviable.

As required under 37 CFR 1.809(d), the specification shall contain: (1) the accession number for the deposit; (2) the date of deposit; (3) a description of the deposited biological material sufficient to identify it and to permit its examination; and (4) the name and address of the depository.

Although, the depository, Belgian Coordinated Collection of Microorganisms, used by Applicants is recognized by the MPEP 2405-8, Applicants have not complied with one or more of the requirements of the Budapest Treaty, 37 C.F.R. 1.801-1.809. Compliance is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite as written. The claim embraces various culturing reagents (for example, such as PBS, D-MEM, MEM and RPMI) by name. The metes and bounds

of the various culturing reagents cannot be determined as the specification has not provided a definition of the composition of the reagents. It appears for example that various forms/compositions of the reagents are commercially available. It is not understood from the claim which form of a particular reagent is being claimed.

Claims 17-19 recite the limitation "the composition" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 20 is incomplete as written. The claim is directed to a method of culturing mammalian ES cells. The claim however provides no method steps that set forth the goal of the preamble rendering the claim incomplete as written. Appropriate correction is required.

Claim 20 is indefinite as written. The claim is directed culturing mammalian ES cells. However the claim recitation of "ES stem cells" is not understood as "ES" is an abbreviation for "embryonic stem". The claim actually reads on embryonic stem stem cells, which does not have a clear meaning and is not an art-recognized term. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-13, 17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hogan et al (1994, Manipulating the Mouse Embryo, A Laboratory Manual, 2nd edition).

The claims are directed to a medium of cell culture reagents comprising leukemia inhibitory factor (LIF), animal serum (particularly fetal bovine serum or FBS), wherein the FBS is treated, a reducing agent, antibiotic, and L-glutamine, wherein the medium may be conditioned by fibroblast transfected with a vector comprising a LIF gene. The claims are further directed to a process of culturing embryonic stem cells.

Claim 1 is a product by process claim directed to a culture medium comprising LIF in which the process of creating the medium carries little patentable weight. Note that it is only the product, which is anticipated by the prior art and not the process by which the product is made. This is because the final product (the culture medium) is not distinguished by any particular features or characteristics as a result of the process by which it is made other than the requirement that it comprises LIF. As such the limitations of the claimed culture medium are met by any culture medium in the prior art comprising LIF. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it, which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985).

Hogan et al teach a medium of cell culture reagents (page 256-257) comprising LIF, wherein the LIF may be added exogenously or is produced by cultured feeder cells that condition said medium (page 258-9), such as STO cells expressing endogenous or

recombinant LIF. On page 256, Hogan et al, teach DMEM plus glucose as a culture medium suitable for culturing ES cells, while on page 257 Hogan lists supplements [such as glutamine, nonessential amino acids, β-meracaptoethanol, gentamycin and serum] to be added the DMEM. In the paragraph bridging pages 257-258, Hogan et al describes the addition of fetal bovine serum to the DMEM. On pages 255-272 Hogan et al provides methodology for culturing mammalian ES cells.

Thus, the teachings of Hogan et al meet all of the instant claim limitations.

Claims 1-11, 13 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Galli-Taliadoros et al (Journal of Immunological Methods, 1995, 181: 1-15; IDS).

The claims are directed to a medium of cell culture reagents comprising leukemia inhibitory factor (LIF), animal serum (particularly heat inactivated fetal bovine serum or FBS), a reducing agent, antibiotic, and L-glutamine, wherein the medium may be conditioned by fibroblasts. The claims are further directed to a process of culturing embryonic stem cells.

Claim 1 is a product by process claim directed to a culture medium comprising LIF in which the process of creating the medium carries little patentable weight. Note that it is only the product, which is anticipated by the prior art and not the process by which the product is made. This is because the final product (the culture medium) is not distinguished by any particular features or characteristics as a result of the process by which it is made other than the requirement that it comprises LIF. As such the limitations of the claimed culture medium are met by any culture medium in the prior art

comprising LIF. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it, which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985).

Galli-Taliadoros et al teach a medium of cell culture reagents (page 5, column 1, in the section 2.3) comprising LIF, wherein the LIF may be added exogenously or is produced by cultured feeder cells that condition said medium (see the paragraph bridging pages 4-5), such as STO cells expressing endogenous LIF. On page 5, in section 2.3, Galli-Taliadoros et al teach DMEM plus glucose as a culture medium suitable for culturing ES cells, and list supplements [such as glutamine, nonessential amino acids, β-meracaptoethanol, antibiotics, and serum] to be added the DMEM. On page 4, in column 2, in the 1st paragraph, Galli-Taliadoros et al describes the addition of heat inactivated fetal bovine serum to DMEM. On pages 4-5, Galli-Taliadoros et al provides methodology for culturing mammalian ES cells.

Thus, the teachings of Galli-Taliadoros meet all of the instant claim limitations.

Claims 1-12, 15-16 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Strojek et al (1990; IDS).

The claims are directed to a medium of cell culture reagents comprising leukemia inhibitory factor (LIF), animal serum (particularly fetal bovine serum or porcine serum), a reducing agent, gentamycin, and albumin, wherein the medium may be conditioned by

fibroblasts. The claims are further directed to a process of culturing embryonic stem cells.

Claim 1 is a product by process claim directed to a culture medium comprising LIF in which the process of creating the medium carries little patentable weight. Note that it is only the product, which is anticipated by the prior art and not the process by which the product is made. This is because the final product (the culture medium) is not distinguished by any particular features or characteristics as a result of the process by which it is made other than the requirement that it comprises LIF. As such the limitations of the claimed culture medium are met by any culture medium in the prior art comprising LIF. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it, which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985).

Strojek et al teach a medium of cell culture reagents (pages 902-903) comprising LIF, wherein LIF is produced by cultured feeder cells, such as STO cells (page 903) expressing endogenous LIF, that condition said medium. Although, Strojek et al do not discuss production of LIF by the feeder STO cells it is quite well known in the art that STO cells produce endogenous LIF (see Hogan et al or Galli-Taliadoros above as evidence of LIF production by STO cells). On page 903, Strojek et al teach DMEM plus glucose as a culture medium suitable for culturing ES cells, and list supplements [such as nonessential amino acids, β-meracaptoethanol, antibiotics (gentamycin), and serum] to be added the DMEM. On page 902, Strojek et al describes the addition of heat

inactivated fetal calf serum to DMEM. On page 911, Strojek et al teach the addition of bovine serum albumin to culture medium. The entire Strojek reference is directed to methodology for culturing mammalian ES cells.

Thus, the teachings of Strojek meet all of the instant claim limitations.

Claims 1-7, 9-10, 14, 16 and 20 rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al (US 5,166,065).

The claims are directed to a medium of cell culture reagents comprising leukemia inhibitory factor (LIF), animal serum (particularly fetal bovine serum or chick serum), a reducing agent, and EGTA, wherein the medium may be conditioned by fibroblasts. The claims are further directed to a process of culturing embryonic stem cells.

Claim 1 is a product by process claim directed to a culture medium comprising LIF in which the process of creating the medium carries little patentable weight. Note that it is only the product, which is anticipated by the prior art and not the process by which the product is made. This is because the final product (the culture medium) is not distinguished by any particular features or characteristics as a result of the process by which it is made other than the requirement that it comprises LIF. As such the limitations of the claimed culture medium are met by any culture medium in the prior art comprising LIF. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it, which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985).

Williams et al teach a medium of cell culture reagents (column 3, lines 54-68) comprising LIF, wherein LIF is added exogenously or produced by cultured feeder fibroblasts expressing endogenous LIF, that condition said medium. In column 3, lines 54-68, Williams et al teach DMEM as a culture medium suitable for culturing ES cells, and list supplements [such as β-meracaptoethanol and serum, particularly fetal calf serum] to be added the DMEM. See column 5 as well. In column 7, Williams et al describes picking of individual ES cell colonies from DMEM/LIF medium and transferring said individual colonies to phosphate-buffered saline/0.5mM EGTA for 5 min and then preparing cell suspensions from the colonies by incubation in trypsin-EDTA with 1% chick serum. It appears the transferred ES cell colony would comprise LIF as it was transferred from medium containing LIF. The Williams reference as a whole is directed to methodology for culturing mammalian ES cells.

Thus, the teachings of Williams meet all of the instant claim limitations.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is (571) 272-0732. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Peter Paras, Jr.

Art Unit 1632

PETER PARAS
PATENT EXAMINER